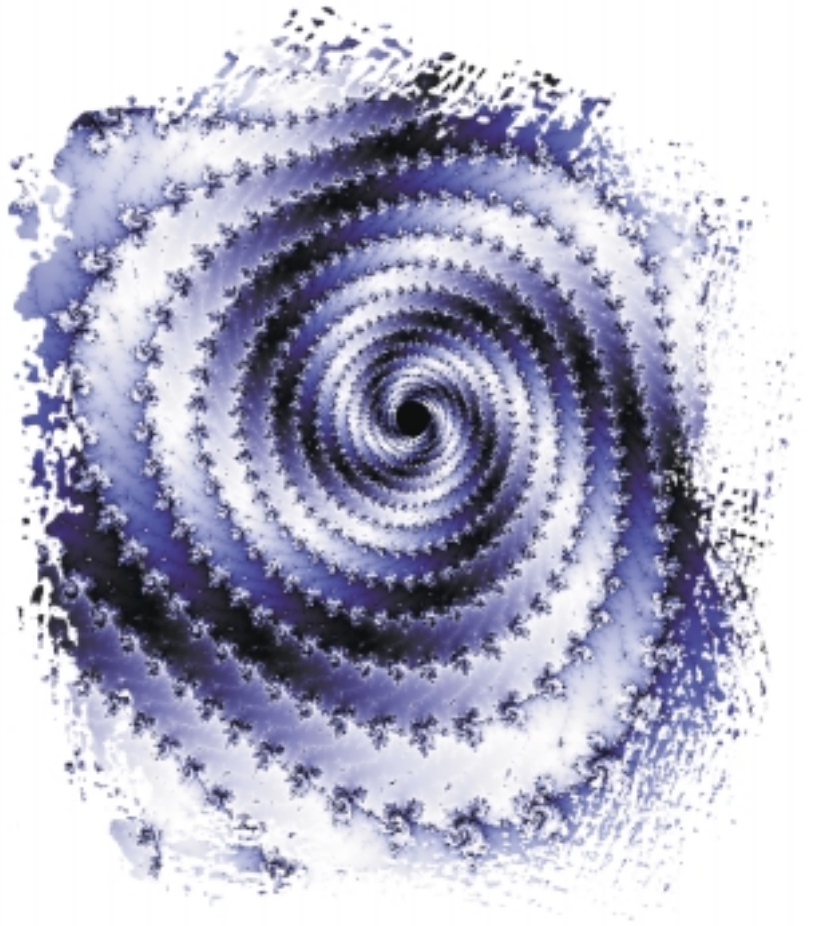


ISO 9001

The Standard Illustrations

The International Standard for
Quality Management Systems



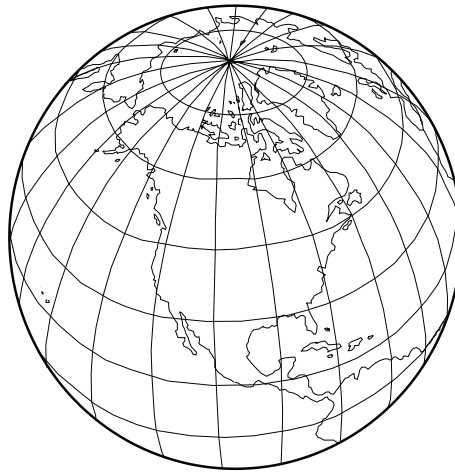
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ISO 9001, The Standard Illustrations

Figures excerpted from
ISO 9001, The Standard Interpretation
Third Edition

by Leland R. Beaumont



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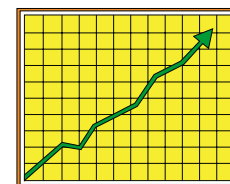
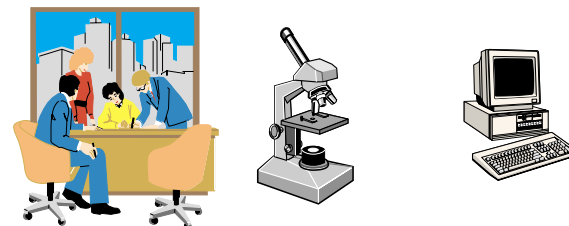
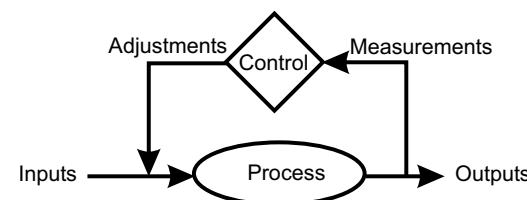
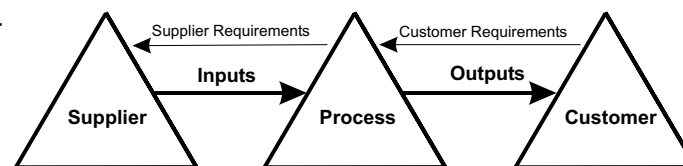
Other books by this author, published by ISO Easy:

ISO 9001, The Standard Interpretation

ISO 9001, The Standard Companion

4.1 General Requirements for the Quality Management System

- Establish, document, and implement a quality management system and continually improve its effectiveness.
- Identify the processes needed to perform the work.
- Determine how these processes are applied throughout the organization.
- Determine their sequence and interaction.
- Determine how the effective operation and control of these processes will be ensured.
- Monitor, measure, and analyze these processes.
- Make available the materials, people, skills, equipment, time, and information needed to operate and monitor these processes.
- Work to achieve the planned results from these processes.
- Continually improve the operation of these processes.



4.2 Documented Quality System

This type of document . . .

Quality Policy

- Defines commitment to quality by top management
- Authorizes the organization to comply with requirements and continually improve

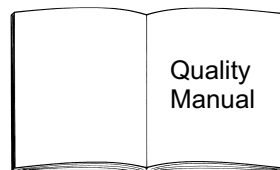


Fulfills these requirements . . .

- Is defined and reviewed by top management (5.1)
- Establishes appropriate commitment to quality (5.3a,b)
- Provides framework for setting quality objectives (5.3c)

Quality Manual

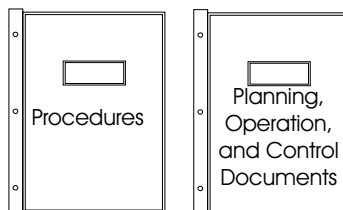
- Defines the scope of the quality management system
- Outlines documentation related to the Standard



- Describes the scope of the quality management system
- Includes or references documented procedures
- Describes how processes interact to form the quality management system

Documented Procedures

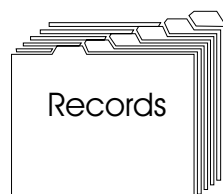
- To meet all the requirements of the Standard
- Others needed for planning, operation and control of processes



- Interact to form an effective quality management system (4.1)
- Referenced by the quality manual (4.2.2)
- Authorized prior to distribution (4.2.3a)

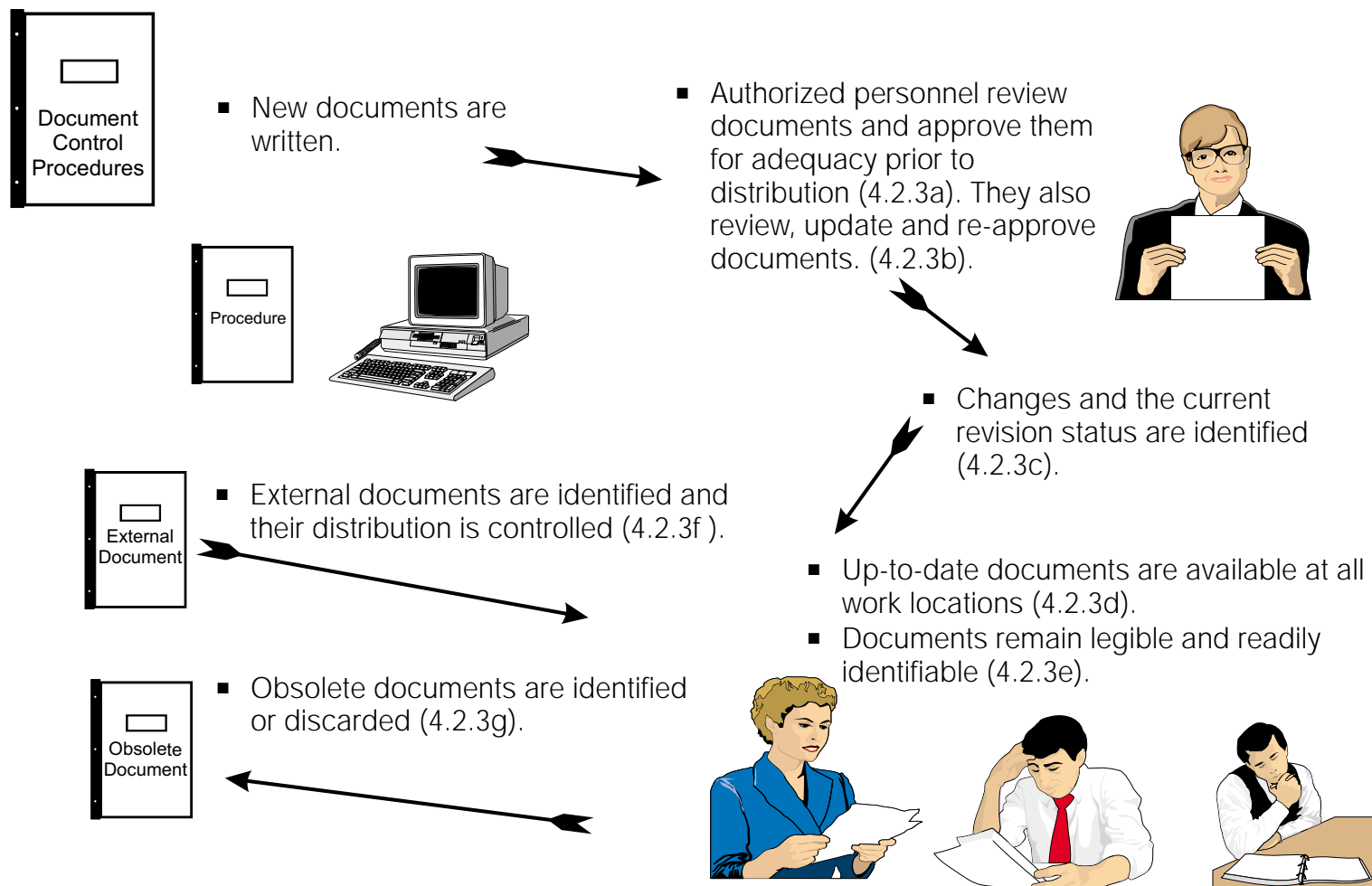
Records

- Result from use of the system



- Are legible, readily identified, stored, protected, readily retrievable, with defined retention times and disposition (4.2.4)

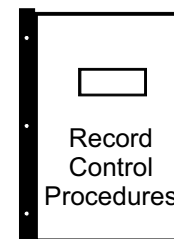
4.2.3 Document Control System



4.2.4 Records Control System

Demonstrates

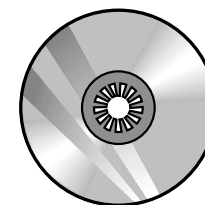
- Conformance to requirements
- Effective operation of the quality management system



- Legible
- Readily identifiable
- Readily retrievable



- Identified
- Stored
- Protected
- Retrievable
- Defined retention time



- May be on electronic media

5 Management Responsibility

5.1 Management Responsibility

- Communicate the importance of meeting requirements
- Establish the quality policy
- Establish quality objectives
- Conduct management reviews
- Provide adequate resources



5.2 Customer Focus

- Understand and meet customer requirements
- Enhance customer satisfaction



5.3 Quality Policy

- Appropriate to the purpose of the organization
- Includes a commitment to meet requirements and improve quality system
- Helps establish and review quality objectives
- Is communicated and understood throughout the organization
- Is reviewed and evolves to remain suitable

5.4 Planning

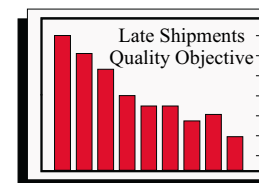
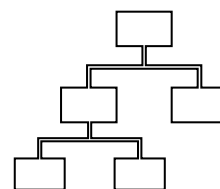
5.5 Responsibility, Authority and Communication

5.6 Management Review

5.4 Planning

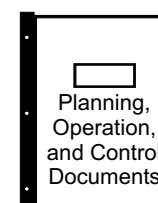
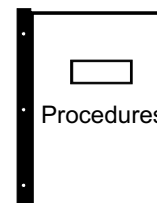
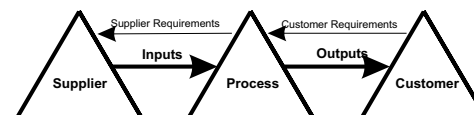
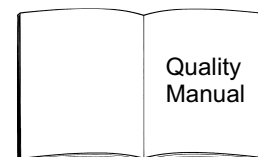
5.4.1 Establish Quality Objectives

- Objectives are established for all relevant functions and levels.
- Product objectives are included (see 7.1a).
- Objectives can be measured.
- Objectives are consistent with the quality policy.



5.4.2 Plan the Quality System

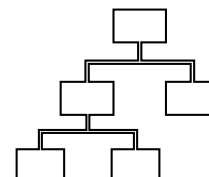
- Top management ensures that the quality management system plans include all the general requirements for the quality management system described in section 4.1.
- Top management also ensures that the current quality management system continues to work effectively while changes and improvements to it are being planned and carried out.



5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

- Responsibility and authority is defined for people whose work affects product and service quality.
- This responsibility and authority is communicated within the organization.



5.5.2 Management Representative

- Is a manager appointed by top management
- Ensures that quality management processes are established, implemented and maintained
- Reports to top management on the performance of the quality management system
- Identifies and reports to top management on any need to improve the quality management system
- Ensures that members of the organization are aware of customer requirements
- May act as liaison to the registration agency and other external organizations regarding the quality management system



5.5.3 Internal Communication

- Appropriate channels of communication are established.
- Communication regarding the effectiveness of the quality management system takes place.



5.6 Management Review

5.6.1 General Management Review Requirements

Top management reviews the quality management system:

- At planned intervals
- To ensure its continuing suitability, adequacy, and effectiveness
- To assess opportunities for improvement and the need for changes in the quality management system; including the quality policy and quality objectives

5.6.2 Review Input

Management reviews Information regarding:

- Audit Results
- Customer Feedback
- Process performance
- Product conformity
- Preventive and corrective action status
- Follow-up actions from previous reviews
- Changes that could affect the quality management system
- Recommendations for improvement



5.6.3 Review Output

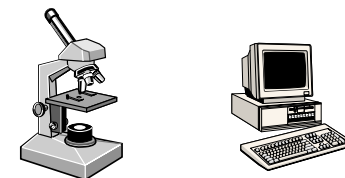
Results are decisions and actions regarding:

- Improvement of the effectiveness of the quality management system
- Improvement of product to better meet customer requirements
- Needed resources

6 Resource Management

6.1 Provide Resources

- To implement and maintain the quality management system
- To continually improve effectiveness of the quality management system
- To enhance customer satisfaction by meeting customer requirements



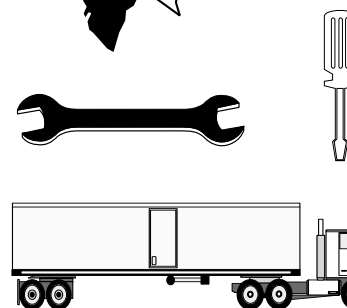
6.2 Provide Competent People



6.3 Infrastructure

Determine, provide and maintain infrastructure, including:

- Buildings, workspace and associated utilities
- Process equipment, including hardware and software
- Supporting services, such as transport or communication, as needed to conform to product requirements



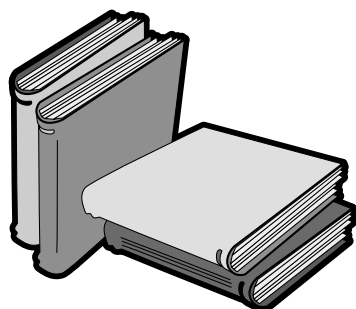
6.4 Work Environment

- Determine and manage the work environment needed to meet product requirements.

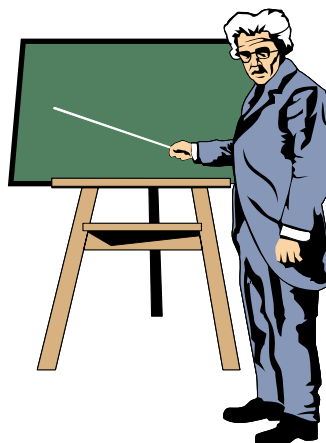


6.2 Human Resources

People whose work affects product or service quality must be competent for that work, based on education, training, skills, and experience.



- Identify required competencies, including training needs.



- Satisfy competency requirements through training or other actions.
- Evaluate the effectiveness of these actions.
- Make certain that people understand how their work contributes to quality objectives.



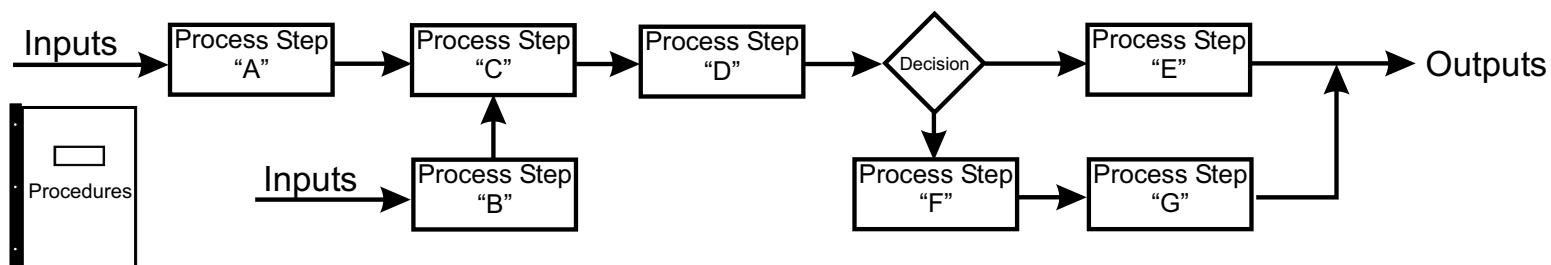
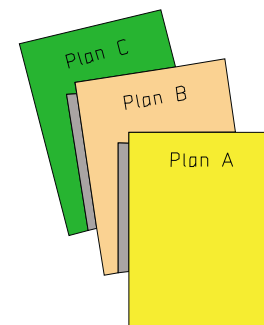
- Maintain records of training, skills and experience.

7.1 Planning Production Processes

- Plan and develop processes needed to create products and deliver service.
- Plan these processes as part of the quality management system.

Determine:

- Quality objectives
- Processes, documents, and resources



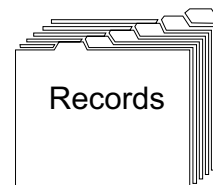
- Verification, validation, monitoring, inspection, and test activities



- Acceptance Criteria



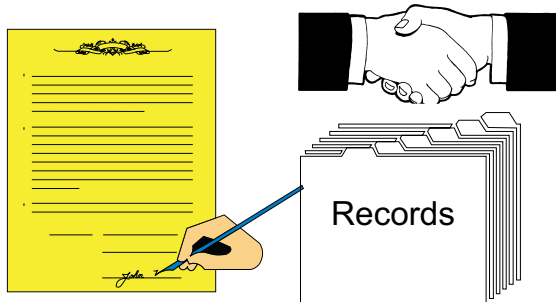
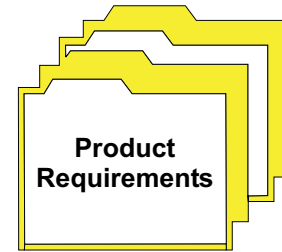
- Records of Conformity



7.2 Customer Relationship Processes

7.2.1 Identify Product Requirements

- Requirements specified by the customer
- Expected requirements unstated by the customer
- Legal and regulatory requirements
- Any additional requirements



7.2.2 Review Product Requirements

Before committing to provide product, ensure that:

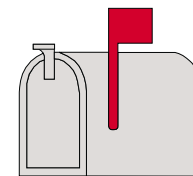
- Product requirements are defined.
- Contract or order changes are understood and resolved.
- The organization has the ability to meet the requirements.

Keep records of the requirements review.

7.2.3 Establish Customer Communication

Establish effective communications with the customer regarding:

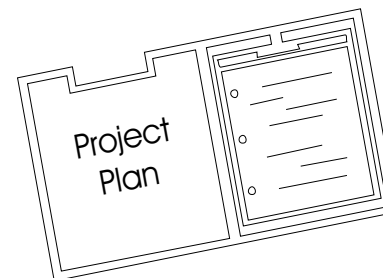
- Product information
- Inquiries, contracts, order handling, job order changes
- Customer feedback and complaints



7.3 Design Control System

7.3.1 Plan the design and development process

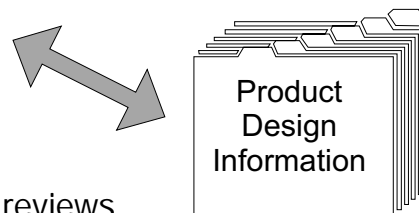
- Development stages, review, verification, and validation activities
- Responsibilities and authorities
- Identification of the organizations involved in design and development
- Description of information flow to carry out the design project
- Transmission of the necessary information among organizations



7.3.2 Create clear design input requirements — written, complete, clear, reviewed. Include function and performance requirements, as well as statutory, regulatory, and other essential requirements.



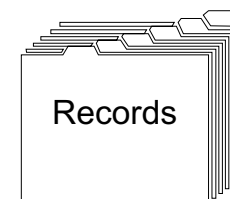
7.3.3 Create design output that meets design stage input requirements and can be verified against those requirements.



7.3.4 Review design results with representatives concerned with the design stage. Record these reviews.



7.3.5 Verify the design to establish that design output meets design input requirements. Record the results.



7.3.6 Validate that the product meets known user needs and requirements. Record the results.



7.3.7 Review, evaluate, approve and record all design changes.

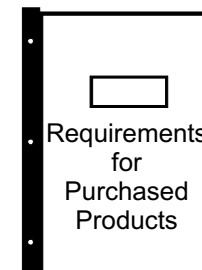
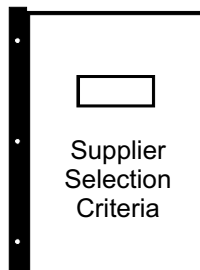
7.4 Purchasing System

7.4.1 Purchasing Process

- Controls ensure that purchased products and services conform to requirements.

Select vendors based on their ability to meet requirements, including quality requirements.

- Define controls over vendors based on type of purchased material, its impact on the final product, and the vendor performance record.
- Establish criteria for selecting, evaluating and re-evaluating vendors.



PURCHASE ORDER			
VENDOR		DATE	
QTY	DESCRIPTION	PRICE	AMOUNT
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			

7.4.2 Complete and Accurate Purchasing Information

Purchasing documents clearly describe the product ordered.

- Requirements for approval of product, procedures, processes, and equipment
- Requirements for qualifying personnel
- Quality management system requirements
- Accuracy assured prior to release

7.4.3 Verify Purchased Product

- Verify incoming material before use.
- You or your customer may arrange to verify product at the supplier's site.



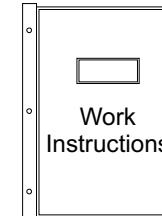
7.5.1 Production Process Control

Carry out production and service processes under controlled conditions.

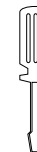
- Information that describes product characteristics is available



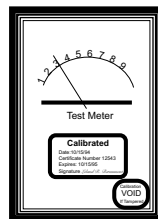
- Documented work instructions define the manner of production, installation, and servicing as needed



- Suitable production, installation, and servicing equipment

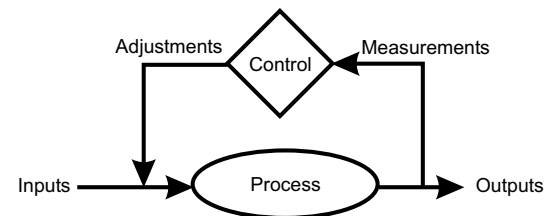


- Availability and proper use of monitoring and measuring devices



- Process parameters and product characteristics are monitored and measured

- Authorization to release the product for shipping
- Follow through on product delivery and post-delivery activities



7.5.2 Validate Special Processes

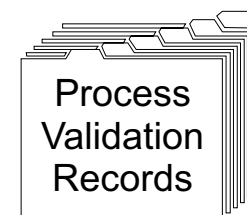
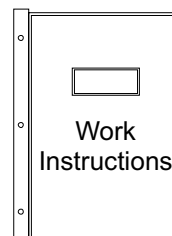
- Identify all “special processes” — where deficiencies become apparent only after delivery or use.
- Validate all of these “special processes” to demonstrate their ability to achieve planned results.
- Establish how each process will be validated, using the following methods as applicable.

- Review and approve process design and implementation.



- Approve equipment and selection of qualified personnel.

- Use specific methods and procedures.
- Establish requirements for record keeping.
- Have criteria for revalidating the process capability.



7.5.3 Identify Product Throughout Production



Identify product testing, measurement, and monitoring status if required by:

- The customer
- Regulatory requirements
- Industry practice

Identify the Product from the time it is received and during all stages of production, delivery and installation.



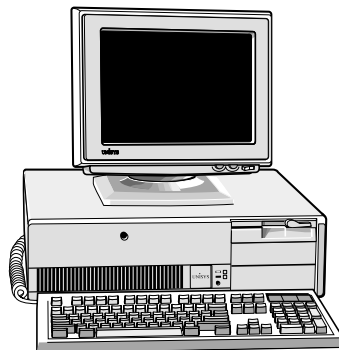
Product History Tracking Record

Serial No.	Batch No.	Shift	Operator	Inspector	Shipper	Hospital
123	55872	Third	Jones	Smith	UPS	Doctors
124	55873	Second	Doe	Wesson	UPS	General
125	55874	Second	Doe	Smith	FedEx	Doctors

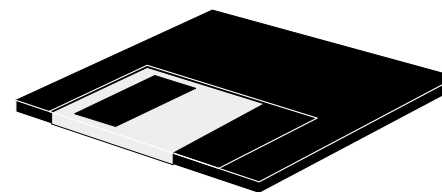
7.5.4 Protect Customer-Owned Property



Customer intellectual property

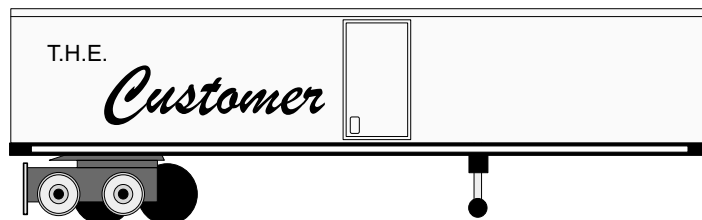


Customer-provided equipment or materials



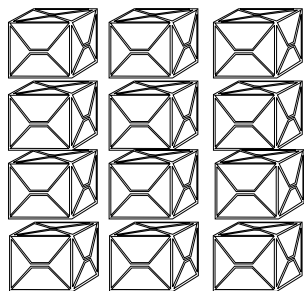
Customer-provided software

Customer-provided shipping systems

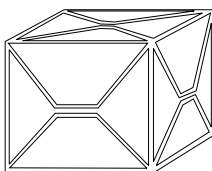


- Identify, verify, protect, and safeguard customer-supplied product for use in the final product.
- Record and report to the customer any lost, damaged, or unsuitable product.

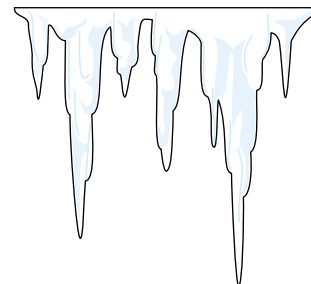
7.5.5 Product Preservation



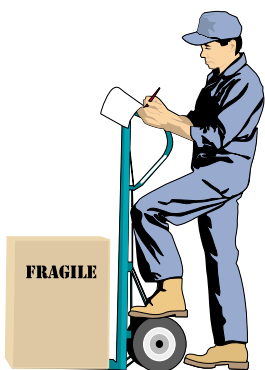
- Prevent damage or deterioration during processing and storage.



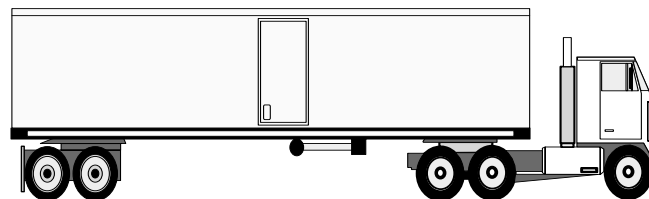
- Control product packaging.



- Preserve the product.

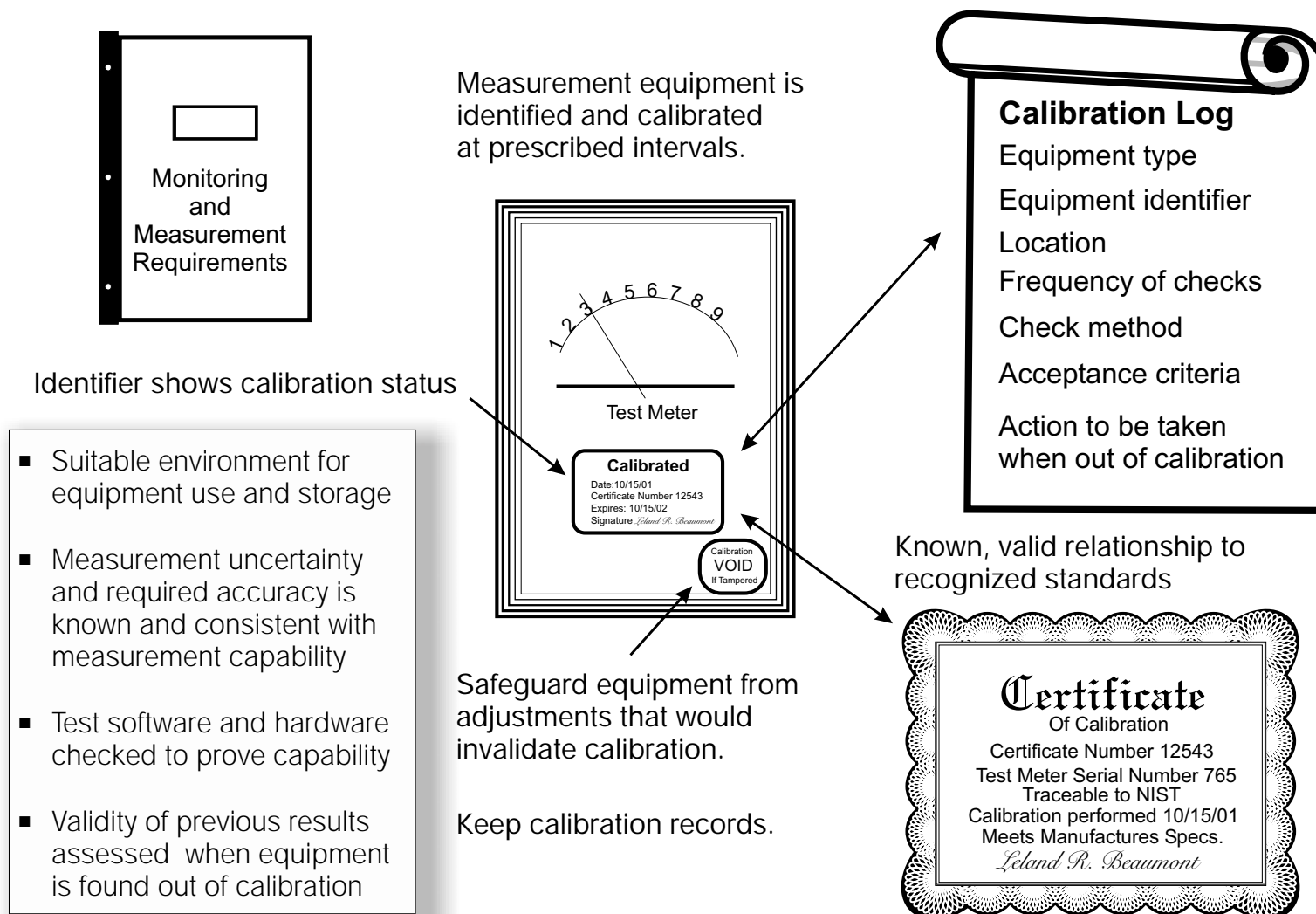


- Prevent damage during product handling.



- Protect product during delivery.

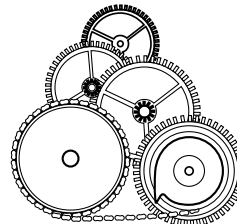
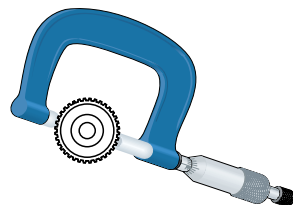
7.6 Measurement Control System



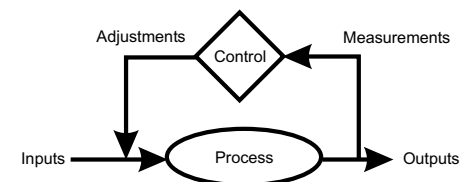
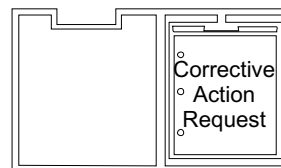
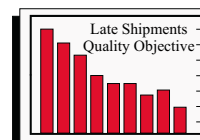
8.1 Measure, Understand and Improve

Plan and carry out inspection, testing, measurement, analysis, and improvement processes.

- Demonstrate that products and services meet defined requirements.



- Sustain the effectiveness of the quality management system.
- Continually improve the effectiveness of the quality management system.



8.2 Monitor and Measure

8.2.1 Measure Customer Satisfaction

- Determine how to measure and use this information.
- Measure customer perception regarding meeting customer requirements.



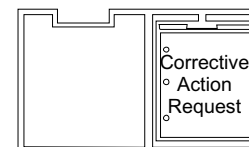
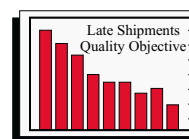
Dissatisfied Satisfied
1 2 3 4 5 5 7

8.2.2 Conduct Internal Audits

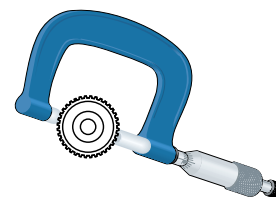


8.2.3 Monitor and Measure Quality Management Processes

- Demonstrate ability to meet planned results.
- Take corrective and preventive action when planned results are missed.



8.2.4 Monitor and Measure the Product



8.2.2 Internal Audit System

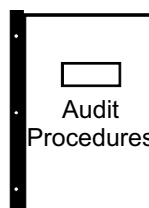
- Determine if quality activities and related results comply with planned arrangements.
- Determine the effectiveness of the quality management system.

January 1995						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

- Schedule audits on the basis of status and importance of the activity being audited.
- Consider results of previous audits.
- Define criteria, scope, frequency, and method.

Auditors:

- Follow a defined procedure.
- Observe work practices.
- Examine records.
- Identify nonconformities.

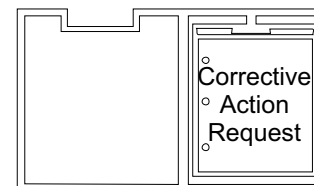


Audit results are:

- Recorded.
- Brought to the attention of those having responsibility for the area audited.
- Corrective and preventive action is taken promptly.
- Follow-up ensures improvement.

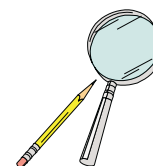
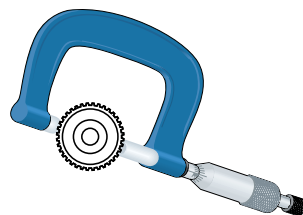
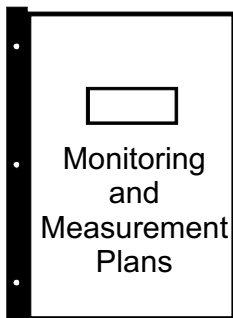


- Top Management reviews the effectiveness of the quality management system (5.6).

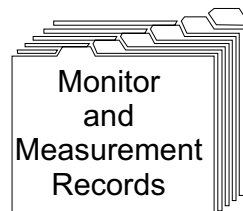


8.2.4 Monitoring and Measuring Products

Plan and carry out inspection, test, and measurement of product and service characteristic at all appropriate stages of production.

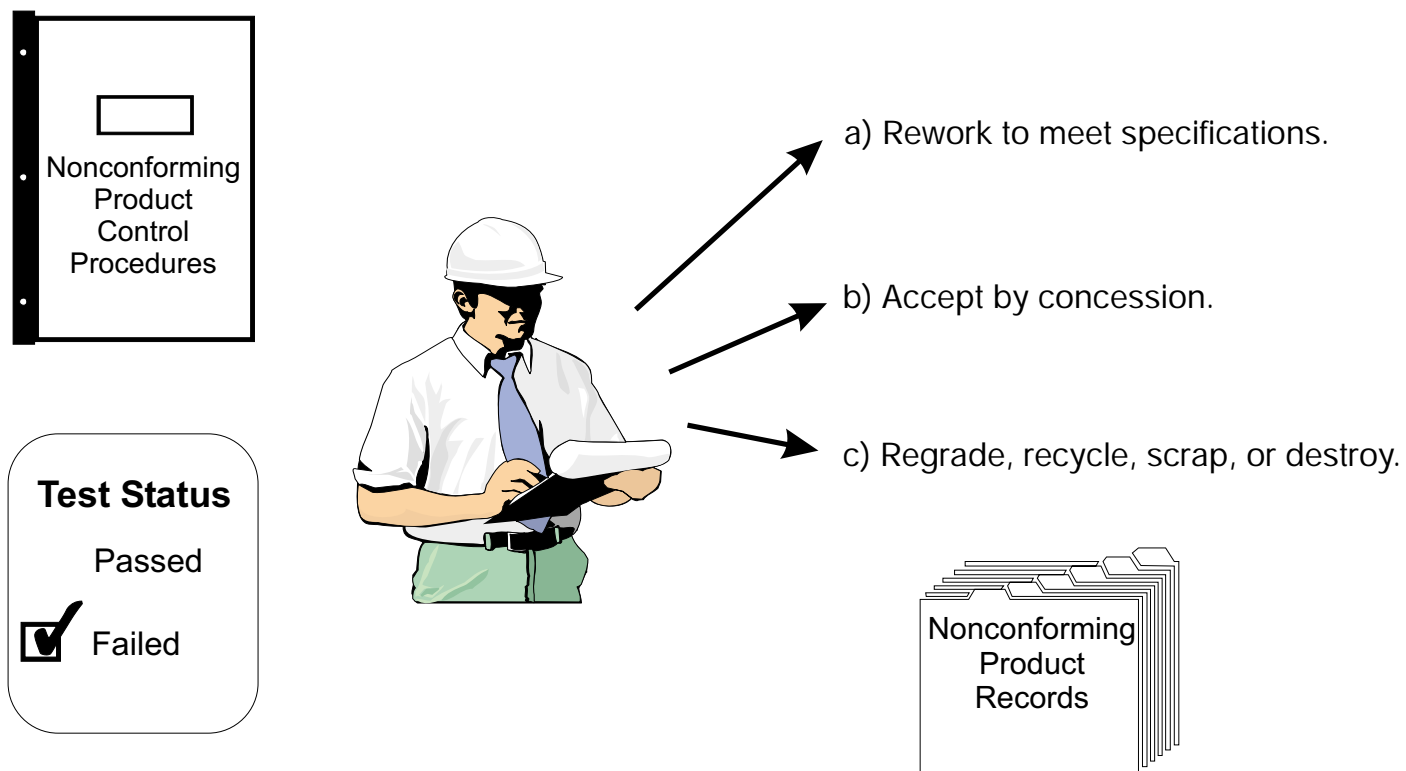


- Retain evidence the products meets the acceptance criteria.
- Maintain inspection, test, and measurement records.
- Record who authorized release of the product.
- Identify and maintain monitoring and measurement status (7.5.3).



- Complete all testing before releasing the product.

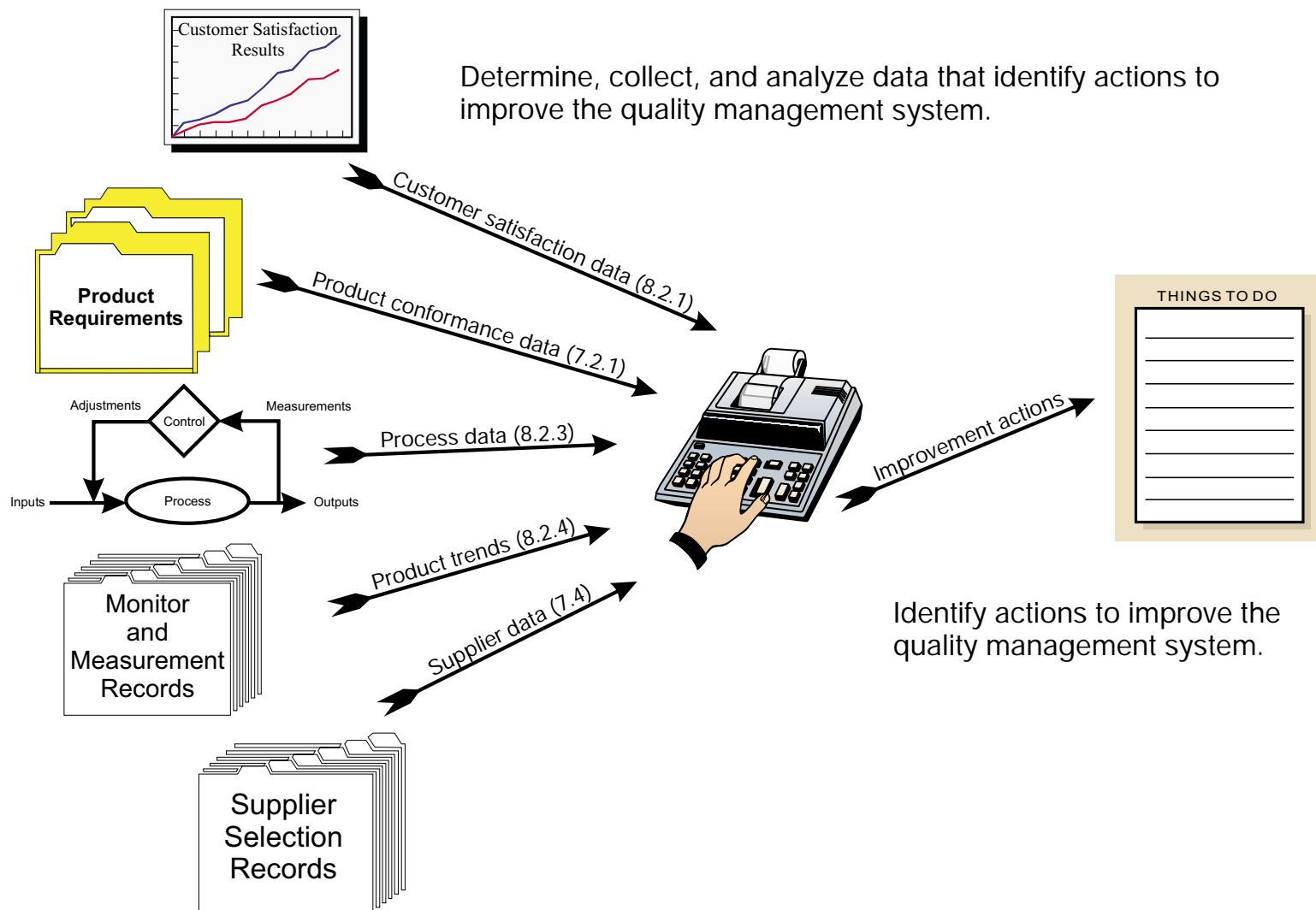
8.3 Handling Nonconforming Product



Recall or otherwise reduce the impact of nonconforming product that has been delivered to customers.

- Reinspect repaired product.
- Report nonconforming product as required by contract.

8.4 Data Analysis



8.5.1 Continual Improvement

Effectiveness of the quality management system is continually improved upon.

5.3 The quality policy establishes a commitment to continuous improvement.

5.4.1 Quality objectives establish measurable goals.

8.2.2 Audits assess the effectiveness of the quality management system.

8.4 Information regarding the following is analyzed and understood.

- Customer satisfaction (8.2.1)
- Product conformance (7.2.1)
- Product characteristics and trends (8.2.3)
- Process characteristics and trends (8.2.4)
- Supplier performance (7.4)

7.2.3 Customer feedback is gathered and customer complaints are reviewed (8.5.2).

8.3 Nonconforming product is controlled and recorded.

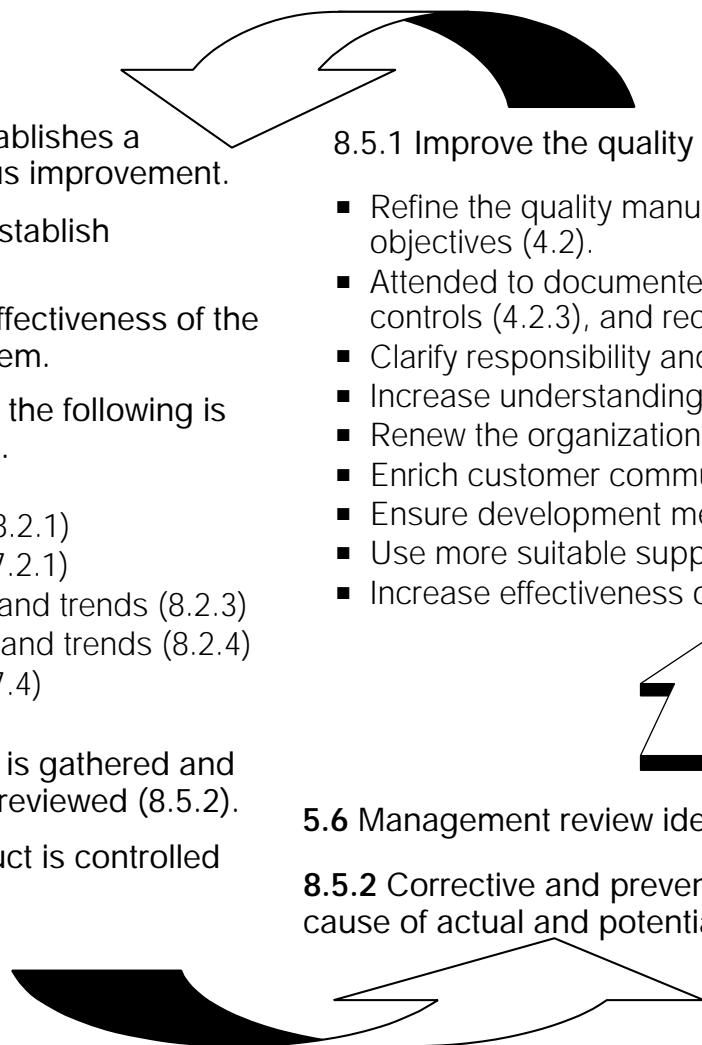
4.2.4 Records are kept.

8.5.1 Improve the quality management system.

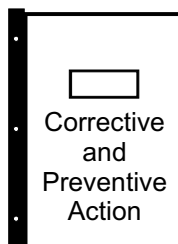
- Refine the quality manual, quality policy, and quality objectives (4.2).
- Attended to documented procedures (4.2.1), document controls (4.2.3), and record keeping (4.2.4).
- Clarify responsibility and authority (5.5).
- Increase understanding of human resource needs (6.2).
- Renew the organization's infrastructure (6.3).
- Enrich customer communication (7.2).
- Ensure development meets customer needs (7.3).
- Use more suitable suppliers and specific supplies (7.4).
- Increase effectiveness of production processes (7.5).

5.6 Management review identifies improvements.

8.5.2 Corrective and preventive action eliminates the cause of actual and potential nonconformities.

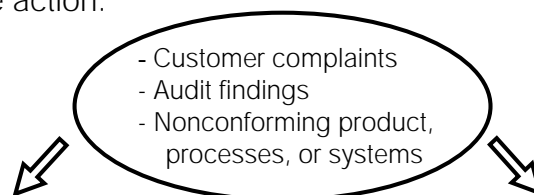


Corrective and Preventive Action



Procedures describe corrective and preventive action.

- Actions are appropriate to the impacts of the nonconformities.
- Record changes in documented procedures resulting from corrective and preventive action.



Eliminate the cause of *existing* nonconformity.

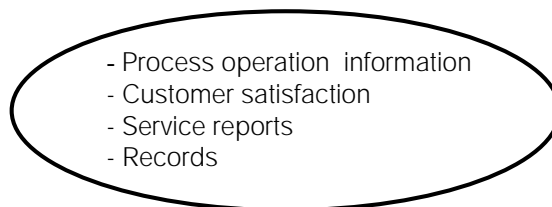
Eliminate the cause of *potential* nonconformity.

8.5.2 Corrective action is taken.

- Resolve complaints and nonconformities.
- Investigate causes of nonconformity.
- Record results of investigations.
- Corrective action is determined, carried out, effective, and reviewed.

8.5.3 Preventive action is taken.

- Use information from many sources to detect, analyze, and eliminate potential causes.
- Identify steps needed to prevent problems.
- Carry out the preventive action.
- Ensure preventive action is effective.
- Actions taken are recorded and reviewed.



Top management reviews the effectiveness of the quality management system (5.6).